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510(k) Summary

Submitted by: DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581
Phone: (305) 269-6386
Fax: (305) 269-6441

Contact Person: Suzana Otaño, Project Manager, Regulatory Affairs

Date Prepared: April 14, 2011

General Provisions The name of the device is:

Proprietary Name	Common or Usual Name
ORTHOSORB® Resorbable Pins	Pin, Fixation, Resorbable, Hard Tissue

Name of Predicate Devices The device is substantially equivalent to the currently marketed ORTHOSORB Resorbable Pin, K901456.

Classification Class II, Regulation Number 21 CFR 888.3040, Product Code OVZ

Performance Standards Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act for these devices.

Device Description The ORTHOSORB 1.3mm and 2.0mm Resorbable Pins are made from poly-p-dioxanone and are available in 1.3mm and 2.0mm diameters and 40mm and 50mm lengths with their accompanying instrumentation.

Indications for Use The ORTHOSORB Resorbable pin are indicated for use to fix in place small bony or chondral fragments in the knee and hand where such fragments are not in tension, as in the case of osteochondritis dissecans or fractures of the phalanges and metacarpals; or for fixation of inherently stable osteotomies of the great toe and intramedullary stability of joint arthroplasty (resection) for the treatment of lesser toe deformities. The Resorbable Pin can be used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are also employed.

Technological Characteristics The technological characteristics of the ORTHOSORB Resorbable pins that are the subject of this submission remain unchanged from the predicate device in terms of design, material and performance.

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Summary of Substantial Equivalence	The ORTHOSORB Resorbable pins that are the subject of this submission are equivalent to the predicate device. The technological characteristics are identical. Based on material, the pins are considered MR Safe as defined in ASTM F2503.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUL 12 2011

DePuy Orthopaedics, Inc.
% Ms. Suzana Otaño
700 Orthopaedic Drive
Warsaw, IN 46581-0988

Re: K111077
Trade/Device Name: ORTHOSORB Resorbable Pin
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: OVZ
Dated: April 14, 2011
Received: April 18, 2011

Dear Ms. Otaño,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K111077

Device Name: **ORTHOSORB Resorbable Pin**

Indications For Use:

The ORTHOSORB Resorbable pin are indicated for use to fix in place small bony or chondral fragments in the knee and hand where such fragments are not in tension, as in the case of osteochondritis dissecans or fractures of the phalanges and metacarpals; or for fixation of inherently stable osteotomies of the great toe and intramedullary stability of joint arthroplasty (resection) for the treatment of lesser toe deformities. The Resorbable Pin can be used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are also employed.

Prescription Use X AND/OR Over-the-Counter _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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